

Claims:

1. An assay for testing a subject for diabetes or a predisposition to diabetes comprising:
analysing a biological fluid from a subject for the presence of one or more
proteins selected from the group consisting of Alpha 2 macroglobulin, Apolipoprotein
A1, Immunoglobulin alpha heavy chain constant region, Immunoglobulin mu chain C
region, Chain A of Human IgA1, Inter-alpha-trypsin inhibitor heavy chain H4
precursor, and Apolipoprotein B-100;
wherein detection of the protein is indicative of diabetes or a predisposition to
diabetes in the subject.
2. The assay according to claim 1 wherein the one or more proteins are detected by the
presence of a peptide marker selected from the group consisting of:
AYIFIDEAHITQALIWLSQR (SEQ ID NO:1),
LLIYAVLPTGDVIGDSAK (SEQ ID NO:2),
LLLQQVSLPELPGEYSMK (SEQ ID NO:3),
QGLLPVLESFK (SEQ ID NO:4),
LLDNWDSVTSTFSK (SEQ ID NO:5),
KEPSQGTTFFAVTSILR (SEQ ID NO:6),
VFAIPPSFASIFLTK (SEQ ID NO:7),
QEPSQGTTFFAVTSILR (SEQ ID NO:8),
WLQGSQELPR (SEQ ID NO:9),
LWAYLTIQQLLEQTVSASDADQQALR (SEQ ID NO:10),
AEAQAQYSAAVAK (SEQ ID NO:11),
YSQPEDSLIPFFEITVPESQLTVSQFTLPK (SEQ ID NO:12), and
IAIANIIDEIIEK (SEQ ID NO:13).
3. The assay according to claim 1 or 2 wherein biological fluid is selected from the
group consisting of urine, saliva, blood, blood products, serum, plasma, tears,
cerebrospinal fluid, and lymph.
4. The assay according to claim 3 wherein the biological fluid is urine.
5. The assay according to any one of claims 1 to 4 wherein the biological fluid is
processed prior to analysis.
6. The assay according to claim 5 wherein the biological fluid is concentrated by
membrane-based electrophoresis, TCA precipitation or acetone precipitation.

7. The assay according to any one of claims 1 to 6 wherein proteins present in the biological fluid are digested to form peptide fragments which are detected by conducting mass spectrophotometric analysis on the digested sample.
8. The assay according to any one of claims 1 to 7 wherein the subject is a human.
- 5 9. An isolated peptide marker detectable in a biological sample of a subject and being indicative of diabetes or a predisposition to diabetes in a subject comprising one or more of the following amino acid sequences:
AYIFIDEAHITQALIWLSQR (SEQ ID NO:1),
LLIYAVLPTGDVIGDSAK (SEQ ID NO:2),
10 LLLQQVSLPELPGEYSMK (SEQ ID NO:3),
QGLLPVLESFK (SEQ ID NO:4),
LLDNWDSVTSTFSK (SEQ ID NO:5),
KEPSQGTTFFAVTSILR (SEQ ID NO:6),
VFAIPPSFASIFLTK (SEQ ID NO:7),
15 QEPSQGTTFFAVTSILR (SEQ ID NO:8),
WLQGSQELPR (SEQ ID NO:9),
LWAYLTIQQLLEQTVSASDADQQALR (SEQ ID NO:10),
AEAQAQYSAAVAK (SEQ ID NO:11),
YSQPEDSLIPFFEITYPESQLTVSQFTLPK (SEQ ID NO:12), or
20 IAIANIIDEIIEK (SEQ ID NO:13).
10. An isolated antibody directed to peptide marker according to claim 9.
11. The antibody according to claim 10 being a polyclonal antibody.
12. The antibody according to claim 10 being a monoclonal antibody.
13. The antibody according to any one of claims 10 to 12 being detectably labelled.
- 25 14. An assay for testing a subject for diabetes or a predisposition to diabetes comprising:
obtaining a urine sample from a subject;
concentrating the urine sample;
digesting proteins present in the concentrated urine sample to form peptides;
optionally, separating the peptides; and
30 analysing the peptides for the presence of one or marker peptides having an amino acid sequence of any one of SEQ ID NOS:1 to 13, wherein the presence of marker peptides having an amino acid sequence of any one of SEQ ID NOS:1 to 13 is indicative of diabetes or a predisposition to diabetes in the subject.

15. The assay according to claim 14 wherein the peptides are detected using an antibody directed to a marker peptide having an amino acid sequence of any one of SEQ ID NOS:1 to 13.